UNITED STATES
PATENT AND
TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
WWW.USPTO.GOV

AUG 1 2002

#28

B.J. SADOFF
NIXON & VANDERHYE, P.C.
1100 NORTH GLEBE ROAD, 8TH FLOOR
ARLINGTON, VA 22201-4714

In re Application of	:
ELMORE et al	:
Serial No. 08/981,087	: DECISION ON PETITION
371 Filing Date: 27 May 1998	:
Attorney Docket No. 1498-133	:

This letter is in response to the Petition under 37 CFR 1.144, filed 5 October 2001. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed on 27 May 1998, under 35 U.S.C. 371 as the national stage filing of PCT/GB96/01409, filed 12 December 1997, which claims priority to GB serial number 9511909.5, filed 12 June 1995.

A review of the file history shows that original claims 1-25 were directed a polypeptide free of botulism toxin activity and free of toxoid which induces protective immunity to a type F botulism toxin, pharmaceutical compositions, vaccines comprising such. Polynucleotide molecules encoding such, and methods of producing the polypeptide were also claimed.

A preliminary amendment filed 27 May 1998 as Paper No. 5, added new claims 24-25 and amended the dependencies of claims 1-3, 5-10, 12-14, 16-17, 19-21 and 23.

On 16 June 1999, the Office mailed Paper No. 8, which contained a two-way Restriction Requirement dividing the claims into groups as follows:

> Restriction to one of the following inventions is required under 35 U.S.C. § 121 and 372:

I. Claims 1-12 and 19-24, drawn to polypeptide free of botulism toxin activity, polypeptide composition and vaccine comprising said polypeptide.

II. Claims 13-18 and 25, drawn to recombinant DNA encoding a polypeptide and a method of producing a polypeptide

The groups lack the same or corresponding special technical feature for the following reasons:

The polypeptides of Group I comprise amino acids whereas the recombinant DNA of Group II comprises nucleotides. Further the polypeptides have different functions from DNA, i.e., DNA functions to encode polypeptide.

The examiner also reasoned that East et al teach a polypeptide as recited in claim 1, therefore the polypeptide does not define a contribution over the prior art.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art because of their recognized divergent subject matter and because the literature searches required for examination of the groups identified above are not coextensive, restriction for examination purposes as indicated is proper.

In Paper No. 9, filed 14 September 1999, Applicants elected Group I for examination, with traverse. The traversal was on the grounds that

"[a]pplicants consider the findings of the international search report and the holding of unity of invention to pertain in the present application as well, namely that the two groups of claims [sic, do not] lack the same or corresponding special technical feature."

In Paper No. 10, mailed 7 October 1999, the examiner considered the traversal but found it not persuasive because the technical feature linking Groups I and II was not a contribution over the prior art, in view of East et al. The Restriction Requirement was deemed proper and made Final. Claims 13-18 and 25 were withdrawn under 37 CFR 1.142(b), as being directed to a non-elected invention. Claims 1-7 and 9-10 were rejected under 35 U.S.C. 101, as being directed to non-statutory subject matter. Claims 3-6 were rejected under 35 U.S.C. 112, for scope of enablement. Claims 5, 7-12 and 19-24, and those dependent thereon were rejected under 35 U.S.C. 112, second paragraph for indefiniteness. Claims 1-2, 12 and 22 were rejected under 35 U.S.C. 102(b) as being anticipated by Sesardic et al.

In Paper No. 12, filed 7 January 2000, applicants submitted the first petition under 37 CFR 1.144, which was matched to the file but unfortunately not forwarded promptly for decision. An amendment to the claims was filed 7 January 2000 as Paper No. 13, in which claims 1-7, 9-10, 17, 19 and 21 were amended.

In Paper No. 14, the Office sent out a non-final office action, which acknowledged receipt of the petition and stated that the application would be forwarded for consideration. The traversal of the restriction requirement was considered and found not persuasive. Claims 13-18 and 25 were withdrawn under 37 CFR 1.142(b), as being

directed to a non-elected invention. Claims 1-7 and 9-10 stood rejected under 35 U.S.C. 101, as being directed to non-statutory subject matter. Claims 7 and 9 and those dependent thereon (claims 8 and 10-11) and claims 22-24 were rejected under 35 U.S.C. 112, for scope of enablement. Claims 8, 10, 11 were rejected under 35 U.S.C. 112, second paragraph for indefiniteness. Claims 1-2, 12 and 22 were rejected under 35 U.S.C. 102(a) as being anticipated by Sesardic et al. Claims 3-4, 7-10 and 19-24 were rejected under 35 U.S.C. 102(a) as being anticipated by Sesardic et al, as evidenced by the Sigma catalog 1992. Claims 1-4, 7-12, 19-24 were rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al.

In Paper No. 15, filed 16 June 2000, applicants submitted another amendment which canceled claims 1 and 2, amended claims 3, 7-10, 12-14, 19-20 and added new claim 26.

In Paper No. 16, filed 16 June 2001, applicants added new claims 27-33.

Paper No. 17, mailed 27 February 2001, contained a Notice concerning the sequence requirements.

In Paper No. 18, filed 27 March 2001, Applicants filed a sequence listing.

In Paper No. 19, mailed 5 June 2001, as a final Office action, claims 3-12, 19-24, 26-28 and 30-33 were pending and under examination. Claims 13-18 and 25 remained withdrawn as being directed to a non-elected invention. Applicants were reminded that a complete reply to the final rejection must include cancellation of the non-elected claims or other appropriate action (37 CFR 1.144), citing MPEP 821.01. Claims 22-24 were rejected under 35 U.S.C. 112, first paragraph for scope of enablement. Claims 3-4, 7-10, 12, 19-24, 26-27 and 30-33 were rejected under 35 U.S.C. 102(a) as being anticipated by Sesardic et al as evidenced by Sigma catalog, 1992. Claims 3-4, 7-12, 19-24, 26-27 and 30-33 were rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al. Claims 3-4, 7-10, 12, 19-24, 26-27 and 30-33 were rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. Claims 3-12, 19-24, 26-28 and 30-33 were rejected under 35 U.S.C. 112, second paragraph for indefiniteness. The action was made Final.

In Paper No. 20, mailed 10 August 2001, the Office addressed the Petition filed 7 January 2000. The Petition had requested rejoinder of the DNA and polypeptide claims; this was denied because the polypeptide, as claimed at that time, did not make a contribution over the prior art. The Decision pointed out that the "determination may, therefore, change with each Office action depending upon the prior art discovered and applicants' actions."

On 5 September 2001, Applicants filed Paper No. 21, which proposed cancellation of claims 3, 4, 20, 22-24 and 27 and amendment of claims 5-8, 12, 19, 21, 26, 28, 30-31.

On 4 October 2001, the Office mailed out an Advisory Action, which stated that the proposed amendment would not be entered, in view of new issues raised and the amendments were not deemed to place the application in better condition for appeal by materially reducing or simplifying the issues for appeal.

On 5 October 2001, an amendment to the claims and this petition were filed as Paper Nos. 23 and 24. Unfortunately the petition was not promptly forwarded for decision. The amendment canceled claims 3-4, 20, 22-24 and 27 and amended claims 5-8, 12-14 17, 19, 21, 26, 28 and 30-31. It is noted that claim 29, incorrectly listed as pending by the Petition, was cancelled by Paper No. 18 filed 5 June 2001.

Subsequent to the filing of this petition, an interview took place on 30 October 2001, stating that the after final amendment was received and under review.

On 5 November 2001, a request for continued prosecution application was filed as Paper No. 26.

DISCUSSION

The application, file history and petition have been considered carefully. The petition presents several concerns:

(1) the failure of the Office to timely decide the Petition filed 7 January 2000, thereby resulting in a premature Final Office action;

(2) pursuant to Rule 116(c), a request to amend claims 13, 14 and 17

(3) in the event that the attached amendment was not entered, withdrawal of the finality of the Office action and

(4) a request to have the restriction between Groups I and II withdrawn.

Each concern will be addressed in turn.

Concerning item (1), Applicants argue that the finality of Paper No. 19 was premature in view of fact that an outstanding petition, filed 18 months previous, had not, at the time of Paper No. 19's mail date, been decided by the Office. The Finality of an Office action is results from claim rejections. In contrast, the petition concerned a restriction requirement and not claim rejections. The petition decision did not alter the Finality of the Office action, which was proper. Applicants are correct that the Petition Decision deemed the restriction requirement was proper, between the DNA and polypeptides as defined by the claims pending at the time the restriction requirement was made and that the restriction requirement should be reviewed with each Office action.

Concerning item (2), Applicants' request that the Office enter the amendment presented in Paper No. 21, filed 5 September 2001 is moot in view of the filing and entry of a subsequent Amendment G. The Amendment G filed 5 October 2001 as Paper No. 24, is cumulative to Amendments presented in Paper No. 21. Amendment G resolved all outstanding rejection in the final Office action as follows:

The rejection of Claims 22-24 under 35 U.S.C. 112, first paragraph for scope of enablement was resolved by cancellation of claims 22-24.

The rejections of Claims 3-4, 7-10, 12, 19-24, 26-27 and 30-33

(i) under 35 U.S.C. 102(a) as being anticipated by Sesardic et al as evidenced by Sigma catalog, 1992 and

(ii) under 35 U.S.C. 102(b) as being anticipated by Thompson et al

were resolved by

(1) cancellation of claims 3-4, 20, 22-24 and 27

(2) amendment of claims 7, 9-10, 12, 19, 21 to depend upon non-rejected claim 5

(3) amendment of independent claim 8 to narrow to SEQ ID Nos. 1, 2, 3 or 4, as in non-rejected claim 5.

The rejection of Claims 3-4, 7-12, 19-24, 26-27 and 30-33 under 35 U.S.C. 102(b) as being anticipated by Simon et al was resolved by

(1) cancellation of claims 3-4, 20, 22-24 and 27

(2) amendment of claims 7, 9-10, 12, 19, 21 to depend upon non-rejected claim 5

(3) amendment of independent claim 8 to narrow to SEQ ID Nos. 1, 2, 3 or 4, as in non-rejected claims

(4) amendment of claim 11 to depend upon non-rejected claim 8.

The rejection of Claims 3-12, 19-24, 26-28 and 30-33 under 35 U.S.C. 112, second paragraph for indefiniteness was resolved by

(1) the cancellation of claims 3-4, 20 and 27

(2) removing the offending terms "derivative" and "fragment" from remaining claims.

The amendment in Paper No. 24 also corrected an obvious typographical error, thereby overcoming the objection of claim 8.

One minor error is noted in amended claim 14, where antecedent basis is lacking for the phrase "fragment or derivative."

By way of explanation, the Examiner's review of this application may have been complicated by the following two clerical errors, which will be fixed by the Office: claim 10 exists in two different forms, of which only the version presented by Paper No. 15 is correct. Claim 19 exists in two different forms, of which only the version presented by Paper No 24 is correct.

Concerning Item (4), in view of these amendments, the claims of Group I, directed to the polypeptide, now define a contribution over the prior art. According to PCT Rule 13.2 unity of invention will be fulfilled when the groups are linked by a special technical feature which makes a contribution over the prior art. Moreover, in view of Example 17 in Annex B of the Administrative Instructions, generic DNA sequences encoding specific protein molecules which are a contribution over the prior art, will be considered as sharing a special technical feature with the specific protein molecules. As such, upon review of Paper No. 24, Group I, drawn to the specific polypeptides and Group II, drawn to generic DNA encoding the specific polypeptides should have been rejoined at that time

for concurrent examination. Accordingly, the restriction requirement has been withdrawn between Groups I and II.

Concerning Item (3), Applicants' request to have the finality of the Office action withdrawn is moot in view of the filing of a request for continued prosecution application on 5 November 2001. Filing of a CPA changes the status of this application from one filed under 35 U.S.C. 371 to 35 U.S.C. 111(a). US restriction practice normally would now apply to the instant application. However, in view of the unfortunate prolonged prosecution history, and the fact that Paper No. 24 was filed prior to the CPA request, the Office will consider the polypeptide and DNA encoding such as one invention for purposes of examination of this CPA application. Upon filing of Paper No. 24, in the 371 application, the claims were amended so that the special technical features linking the DNA and polypeptide define a contribution over the prior art. At that time, the Groups I and II should have been rejoined and examined together.

If subsequent examination identifies additional prior art rendering one or more of the claims unpatentable, then this rejoinder is further justified by the fact that the Office should have rejoined the Groups I and II, upon receipt and review of Paper Nos. 23 and 24, prior to the submission of the CPA. Because the Office should have examined the DNA and polypeptide together following receipt of Paper Nos. 23 and 24, the Office cannot now establish a search burden that justifies any division between Group I and Group II in this CPA application.

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above as follows: The restriction requirement between Groups I, polypeptide, and Group II, DNA encoding the polypeptide, has been withdrawn. Claims directed to the specific polypeptides and generic DNA encoding such will be examined together in this application.

Additionally, Applicants' request filed 5 October 2001 for one month refund of $100, for the extension of time, is granted.

The application will be forwarded to the examiner for prompt action consistent with this decision.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, Washington DC 20231 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 308-7230.

Bruce Kisliuk
TC1600 Group Director